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EXAMINER	
LILLING, HERBERT J	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 05/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/848,449	AMBUEL ET AL.	
	Examiner	Art Unit	
	HERBERT J LILLING	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *10-30* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Receipt is acknowledged of the Appellant's Brief filed February 26, 2004.

2. **The finality has been withdrawn and prosecution has been reopened** by the Tech Center Appeals Committee based on the remarks of Appellant and the current record.

3. Claims 1-30 are pending in this application.

Claims 10-30 have been withdrawn.

4. Basically the prior rejections as submitted in the Final Rejection have been maintained or modified based on the remarks of the Appellant. New rejections have been added to the record.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

SCOPE ENABLEMENT PROBLEM

Claims 1-9 are rejected under **35 U.S.C. 112, first paragraph**, because the specification, while being enabling for the specific extract as prepared on page 12 [0042-0045], does not reasonably provide enablement for the claimed product without being in complete compliance with the following paragraphs as to the enabling and written descriptions. The specification does not enable any person skilled in the art to

which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims, see the following paragraphs:

WRITTEN DESCRIPTION

The enablement as well as the written description of the instant specification lack support for the claimed ingredients

The specification lacks adequate written description for the claimed inventions in view of the following points in accordance **with the written description requirements of 35 U.S.C. 112:**

The description must clearly allow persons of ordinary skill in the art to recognize what is claimed with respect to the claimed "extract" in the expression "prokaryotic S-30 extract". Thus, an applicant must comply with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of the ingredients requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it.

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372- 73 (Fed. Cir. 1984) Accordingly, naming a type of material generally known to exist, **in the absence of knowledge as to what that material consists of, that is the □extract□, is not a description of that material.** Applicant is required to give the structure of the extract or ingredients in the extract for an appropriate search and examination of the claimed extract.

Thus, Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The broad generic claim lacks sufficient description to inform a skilled artisan that applicant was in possession of the claimed invention at the time of filing since the specification lacks a sufficient number of species which have been described by

complete structure or sufficient identifying characteristics as to the scope of the claimed extract, thus the description requirement has not been satisfied.

AND

The following is a quotation of the **second paragraph of 35 U.S.C. 112:**

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The language of the claims must make it clear what subject matter the claims encompass to adequately delineate their "metes and bounds" as to the claimed "extract". See, e.g., the following decisions: **In re Hammack**, 427 F 2d. 1378, 1382, 166 USPQ 204, 208 (CCPA 1970); **In re Venezia** 530 F 2d. 956, 958, 189 USPQ 149, 151 (CCPA 1976); **In re Goffe**, 526 F 2d. 1393, 1397, 188 USPQ 131, 135 (CCPA 1975); **In re Watson**, 517 F 2d. 465, 477, 186 USPQ 11, 20 (CCPA 1975); **In re Knowlton** 481 F 2d. 1357, 1366, 178 USPQ 486, 492 (CCPA 1973). The courts have also indicated that before claimed subject matter can properly be compared to the prior art, it is essential to know what the claims do in fact cover. See, e.g., the following decisions: **In re Steele**, 305 F 2d. 859, 134 USPQ 292 (CCPA 1962); **In re Moore** 439 F 2d. 1232, 169 USPQ 236 (CCPA 1969); **In re Merat**, 519 F 2d. 1390, 186 USPQ 471 (CCPA 1975).

As indicated above, the term "extract" in the expression "prokaryotic S-30 extract" lacks sufficient information as to the scope of the claimed "extract" for a proper search and

examination of the claimed inventions. This Examiner has indicated in the previous office action as to this search and examination that cannot be properly made for the claimed inventions.

Claims 1-9 fail to comply with the above decisions.

As noted in the previous Final Rejection that the expression "S-30 extract" does not define the ingredients or components of the claimed products. In accordance with the above decisions, Appellant is required to either:

i. insert the components of t he "S-30 extract" product claim;

or

ii. claim the product for the "S-30 extract" as a product by process.

It is also noted that the expression "S-30 extract" defines a generalized procedure according to Zubay having a number of process steps that includes the centrifuging of the reaction medium at 30,000g for 30 min at 4 deg C. The product for each S-30 extract is essentially different based on variations in the Zubay procedure. Each modification employs a different microorganism, additional agents, or conditions which would essentially inherently yield different products. Appellant's remarks have been considered to be erroneous that all "S-30 extracts" are the same. The prior art on the record usually indicates the procedure whether it is Zubay with any modifications to the procedure, which is satisfactory. This Examiner has also stated in the Final Rejection:

"Applicant can check the references of record which clearly indicates that [the] there are differences in the products based on the strain, method and concentration of salts but the centrifugation is at 30,000g for 30 min at 4 deg C. which is referred as the"S-30 extract".

The expression does not define the product and that the instant specification on page 13, states:

"To sample the prior art, three different commercial S-30 extracts were used from two different manufacturers...."

This above statement clearly states on the record submitted by Appellant that "S-30" extracts are different. As recited on page 3 of the Appellant's Brief:

> "In the Final Office Action to this application, the Examiner maintained the two rejections recited in the earlier non-final action. The rejections are premised under 35 U.S.C. 112, first paragraph and under 35 U.S.C. 112, second paragraph. However, both rejections are premised upon the same objection. The objection being that the term "S-30 extract" lacks sufficient definiteness. In the 112, first paragraph, rejection the Examiner contends that the use of the term "S-30 extract" in the specification renders that specification non-enabling, and therefore insufficient, because the specification fails to specify the materials which make up the S-30 extract. In the rejection under I12, second paragraph, the Examiner rejects the claims of this application on the grounds that use of the term "S-30 extract" does not specify sufficient information as to the scope of the extract."

And further recites:

> In the Final Office Action to this application, the Examiner maintained the two rejections recited in the earlier non-final action. The rejections are premised under 35 U.S.C. 112, first paragraph and under 35 U.S.C. 112, second paragraph. However, both rejections are premised upon the same objection. The objection being that the term "S-30 extract" lacks sufficient definiteness. In the 1 12, first paragraph, rejection the Examiner contends that the

> use of the term "S-30 extract" in the specification renders that specification non-enabling, and therefore insufficient, because the specification fails to specify the materials which make up the S-30 extract. In the rejection under 112, second paragraph, the Examiner rejects the claims of this application on the grounds that use of the term "S-30 extract" does not specify sufficient information as to the scope of the extract.

Appellant states next that :

"An S-30 extract is no more poorly defined than any number of other mixtures, extracts and combinations used in biological systems and in patent claims. While the applicants may not be able to define all of the components of an S-30 extract...." ..**which admission is the point of the above rejection**. Applicant is required to recite the claims as a product by process by inserting a sufficient number of process steps to overcome the deficiencies noted by Appellant. Appellants have refused to insert the process steps into the claims. Appellants have stated that :

> " Any even cursory review of the scientific literature will reveal that the term S-30 extract is widely used in the literature to refer to a cellular extract which is exactly the same extract referred to by the appellants here."

The above statement is erroneous as noted above that there are three different S-30 extracts sold by Novagen and each "S-30 extract" is different from each other.

Appellant has complained "It is manifestly impracticable for the Examiner to require the appellants to give an example of every component falling within the "S-30 extract" which is essentially the requirement for any patented composition. In the absence of a complete knowledge of one or more components, these components can be claimed as product by processes or sufficient information e.g., there are hundreds of patented claims issued by this Examiner as well as other Examiners containing extracts of plant materials claimed by a product by process or even Trademarks of materials that are described only by properties which are reasonable for one of ordinary skilled in the art make and practice the instant inventions. In this case, Applicant has refused to

provide the necessary information. It is noted that the Novagen site for the EcoPro product brochures are drawn to Trademark products that are totally deficient as to the components of the S-30 extract.

In fact the site recites the following:

EcoPro™ T7 System
Enhanced coupled transcription/translation system

The EcoPro™ T7 System represents a significant improvement in coupled *in vitro* transcription/translation. The highly optimized EcoPro T7 extract efficiently synthesize full-length proteins from genes downstream from T7 promoters using circular or linear DNA templates. **The EcoPro extracts are prepared with a proprietary fractionation process** that produces higher protein expression levels and predominantly full-length protein, with a marked reduction in the secondary products that are commonly observed with other prokaryotic *in vitro* expression systems.

Components:

- 1 *or* 4 × 24 rxn EcoPro™ T7 Extract
- 0.1 ml 5 mM Methionine
- 1.5 ml Nuclease-free Water
- 10 µg EcoPro Control DNA
- pkg/12 8-cap Strips
- 1 *or* 3 Aluminum Plate Sealer(s)

The product is a Trademark that does not disclose the components in the extract per se.

Appellant also admits on page 8 that the claims lacks suitable information based on the following statements by Appellant:

> "Furthermore, appellants note that in *In re Bowen* the board's non-enablement was reversed where the "claims literally comprehend numerous polymers in addition to the one specifically described in appellant's specification" because no persuasive reason was given by the Patent Office why the specification does not realistically enable one skilled in the art to practice the invention as broadly as it is claimed. ..The same can be said here with respect to the term "S-30 extract". The only impediments are the time and cost of studies which could be performed by

> "those who were expert in the field and actually working" with S-30 extracts doing coupled transcription-translation experiments, i.e., those skilled in the art. "

In this application, Appellant has stated there is an additional problem other than the basic problem as noted above in that even one of ordinary skilled could not make and practice the instant inventions without additional time and cost. The issue as stated is that one does not know the scope of the ingredients whereas in *In re Bowen* the products were known.

On page 9, second paragraph, Appellant has again stated that "However, it is impossible with precision to define all of the components in a material which was made from living cells." Is totally misleading since as stated above the product of any microorganism can easily be fully described by a product by process without even defining one single component in the mixture or composition obtained from the "living cells". Appellants have refused to submit appropriate process conditions to clearly define the claimed reaction mixture.

The statement on page 11 by Appellant that::

"The combined term "S-30 extract" has a clear meaning in the art, is commonly used in the technology, and is widely referred to I the industry to a specific product."

is not correct since the products per se depend upon the conditions and materials employed. It is a fact that the term is drawn to a generalized procedure whereby a reaction mixture is centrifuged at 30,000g for 30 min at 4 deg C. which is referred as the"S-30 extract".

BEST MODE REJECTION

Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, because the best mode contemplated by the inventor has not been inserted into the claimed language, see page 9 [0032].

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Chen et al "Prokaryotic Coupled Transcription-Translation" , Zubay, "In Vitro Synthesis of Protein in Microbial Systems" or Lesley et al.

Each of the references teaches the preparation of a S-30 extract that is combined with a supplemental mix that has all of the required ingredients. Each of the references further freezes (Lesley employs chilling) the mixture, thaws the mixture and centrifuge the mixture which meets the requirements of obtaining a product that is within the scope of the claimed mixture, Chen et al, see page 675, see Zubay, page 275. and Lesley et al, see page 271 and Table 2, D10 strain.

by or, in the alternative, Claims 1-9 are rejected under 35 U.S.C. 103(a) as obvious over Chen et al "Prokaryotic Coupled Transcription-Translation" , Zubay, "In Vitro Synthesis of Protein in Microbial Systems" each alone or further in view of Lesley et al.

The specification teaches that the S-30 extract will inherently after being fractionated to have the desired properties for performing protein synthesis reactions which includes the precipitation of the undesirable interfering high molecular weight components. It would have been prima facie obvious to employ D10 strain for the S-30 strain of Lesley et al which does not contain any Rnase E that would be within the scope of the claimed language.

7. **No claim is allowed**.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Examiner Lilling whose telephone number is 571-272-0918** and **Fax Number** is (703) 872-9306 or SPE Michael Wityshyn whose telephone number is 571-272-0926. Examiner can be reached Monday-Thursday from about 5:30 A.M. to about 3:00 P.M. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

H.J.Lilling: HJL
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Art Unit **1651**
May 12, 2004

Dr. Herbert J. Lilling
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Group 1600 Art Unit 1651